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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,018	01/07/2002	Seiichi P.T. Matsuda	HO-P02080US1	2605

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BAKER BOTTS L.L.P.  
PATENT DEPARTMENT  
98 SAN JACINTO BLVD., SUITE 1500  
AUSTIN, TX 78701-4039

EXAMINER
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RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/041,018

Applicant(s)

MATSUDA ET AL.

Examiner

Delia M. Ramirez

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,4-18,29,32 and 80-141 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,4-9,11-18,29,32,81-91,93-96,98-100 and 112 is/are allowed.
- 6) ☒ Claim(s) 80,92,97,101-111,113-116 and 118-135 is/are rejected.
- 7) ☒ Claim(s) 10,117 and 136-141 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/7/2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/18/05,6/8/05
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

5.00

## **DETAILED ACTION**

### ***Status of the Application***

Claims 1, 4-18, 29, 32 and 80-141 are pending.

Applicant's amendment of claims 1, 4, 6-7, 9-11, 13-15, 29, cancellation of claims 2-3, 19-28, 30-31, 33-79, and addition of claims 80-141 in a communication filed on 4/18/2005 are acknowledged.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

### ***Information Disclosure Statement***

1. The information disclosure statements (IDS) submitted on 4/18/2005 and 6/8/2005 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Objections***

2. Claim 10 is objected to due to the recitation of "orgasm". It should be amended to recite "organism". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112, Second Paragraph***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 80, 92, 97, 101-111, 113-116, 118-135 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claims 80, 92 (claims 97, 101, 111, 129 dependent thereon) are indefinite in the recitation of "a nucleic acid encoding a upc2-1 allele". The term encompasses a genus of nucleic acids encoding any

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upc2-1 allele. However, as previously indicated, while the term “upc2-1” is applicable to *S. cerevisiae*, these gene nomenclature may not be applicable to other organisms. As known in the art, genes encoding proteins of identical function from different organisms may use different designations. See the teachings of Sousa et al. already discussed. For examination purposes, it will be assumed that the term reads “a nucleic acid encoding an sterol uptake control transcription factor”. Correction is required.

6. Claims 102-111 are indefinite in the recitation of “further comprising a vector having the first/second/third/fourth exogenous nucleic acid and first/second/third/fourth promoter” for the following reasons. The unicellular organism of claim 1, 10, 14, 80, 29, 87, 91, 92 already contains a first/second/third/fourth exogenous nucleic acid and a first/second/third/fourth promoter. Therefore, it is unclear if the unicellular organisms of claims 102-111 have, in addition to the exogenous nucleic acids and promoters already present in them, a vector comprising the same exogenous nucleic acids and promoters. For examination purposes, it will be assumed that the term reads “wherein said first/second/third/fourth exogenous nucleic acid and first/second/third/fourth promoter are contained in a vector”. Correction is required.

7. Claims 113-116, 118-121 are indefinite in the recitation of “organism of claim 1 further comprising a second/third/fourth enhancer....activation of the second/third/fourth nucleic acid” because there is no first/second/third/ enhancer or a third/fourth nucleic acid in the organism of claim 1. The organism of claim 1 cannot have a second/third/fourth enhancer if there is no enhancer in claim 1. Also, claim 1 cannot have a third/fourth enhancer for a third/fourth exogenous nucleic acid if there is no third/fourth nucleic acid in the organism of claim 1. Thus, the recited limitations do not further limit claim 1. In regard to claim 113, it is suggested that claim 113 be dependent on claim 112. Correction is required.

8. Claims 122-135 are indefinite in the recitation of “multicellular organism of claim 1/10/14/80/29/87/91/92” since the organism of claims 1, 10, 14, 80, 29, 87, 91, and 92 is a unicellular

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organism. For examination purposes, it will be assumed that the term “multicellular” reads “unicellular”.

Correction is required.

9. Claims 130-131 are indefinite in the recitation of “wherein at least one exogenous nucleic acid comprises an ATG translation initiation codon...” for the following reasons. According to the specification, the polypeptide of SEQ ID NO: 22 and 383, which are encoded by the polynucleotides of SEQ ID NO: 1 and 361, have a methionine residue at position 1. Therefore, the exogenous nucleic acids of claim 1, i.e. SEQ ID NO: 1 and 361, already have an ATG translation initiation codon. As such, it is unclear as to how claims 130-131 further limit claim 1. For examination purposes, it will be assumed that claims 130-131 are duplicates of claim 1. Correction is required.

10. Claim 133 and 135 are indefinite in the recitation of “organism of claim 1 wherein the single exogenous polynucleotide ....” because there is no antecedent basis for the single exogenous polynucleotide in claim 1. For examination purposes, it will be assumed that claims 133 and 135 are dependent on claim 132. Correction is required.

### ***Double Patenting***

11. Claims 115, 117-121, 133, 136-141 are objected to under 37 CFR 1.75 as being substantial duplicates of other claims as follows: claim 115 is a duplicate of claim 116, claim 117 is a duplicate of claim 112, claim 118 is a duplicate of claim 113, claim 119 is a duplicate of claim 114, claim 120 is a duplicate of claim 115, claim 121 is a duplicate of claims 115 and 120, claim 133 is a duplicate of claim 135, claim 136 is a duplicate of claim 1, claim 137 is a duplicate of claim 116, claim 138 is a duplicate of claim 10, claim 139 is a duplicate of claim 17, claim 140 is a duplicate of claim 14 and claim 141 is a duplicate of claim 18. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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*Allowable Subject Matter*

12. The subject matter of claims 1, 4-10, 11-18, 29, 32, 81-91, 93-96, 98-100, 112, 117, 136-141 appear to be allowable over the prior art of record.

*Conclusion*

13. Applicant's amendment adding claims 80-141 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (571) 273-8300. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED**, so as to avoid the processing of duplicate papers in the Office.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from

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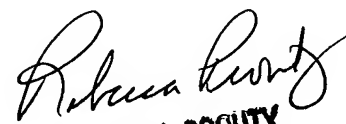
either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Delia M. Ramirez, Ph.D.  
Patent Examiner  
Art Unit 1652

DR  
June 23, 2005

  
REBECCA E. PROUTY  
PRIMARY EXAMINER  
GROUP 1800  
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